11. Grunkemeier GL, Eric Jamieson WR, Miller DC, Starr A. Actuarial versus actual risk of porcine structural valve deterioration. *J Thorac Cardiovasc Surg*. 1994; 108:709-18.
12. Cohen G, Zagorski B, Christakis GT, Joyner CD, Vincent J, Sever J, et al. Are stentless valves hemodynamically superior to stented valves? Long-term follow-up of a randomized trial comparing Carpentier-Edwards pericardial valve with the Toronto Stentless Porcine Valve. *J Thorac Cardiovasc Surg*. 2010;139:848-59.
13. Matsue H, Sawa Y, Matsumiya G, Matsuda H, Hamada S. Mid-term results of freestyle aortic stentless bioprosthetic valve: clinical impact of quantitative analysis of in-vivo three-dimensional flow velocity profile by magnetic resonance imaging. *J Heart Valve Dis*. 2005;14:630-6.
14. Fries R, Wendler O, Schieffer H, Schafers HJ. Comparative rest and exercise hemodynamics of 23-mm stentless versus 23-mm stented aortic bioprostheses. *Ann Thorac Surg*. 2000;69:817-22.
15. Mohammadi S, Baillot R, Voisine P, Mathieu P, Dagenais F. Structural deterioration of the Freestyle aortic valve: mode of presentation and mechanisms. *J Thorac Cardiovasc Surg*. 2006;132:401-6.
16. Mohammadi S, Tchana-Sato V, Kalavrouziotis D, Voisine P, Doyle D, Baillot R, et al. Long-term clinical and echocardiographic follow-up of the Freestyle stentless aortic bioprosthesis. *Circulation*. 2012;126(11 Suppl 1):S198-204.
17. Anselmi A, Flécher E, Ruggieri VG, Harmouche M, Langanay T, Corbineau H, et al. Long-term results of the Medtronic Mosaic porcine bioprosthesis in the aortic position. *J Thorac Cardiovasc Surg*. 2013 Aug 26 [Epub ahead of print].
18. Blais C, Dumesnil JG, Baillot R, Simard S, Doyle D, Pibarot P. Impact of valve prosthesis-patient mismatch on short-term mortality after aortic valve replacement. *Circulation*. 2003;108:983-8.
19. Ennker JA, Ennker IC, Albert AA, Rosendahl UP, Bauer S, Florath I. The Freestyle stentless bioprosthesis in more than 1000 patients: a single-center experience over 10 years. *J Card Surg*. 2009;24:41-8.
20. Bridges CR, O'Brien SM, Cleveland JC, Savage EB, Gammie JS, Edwards FH, et al. Association between indices of prosthesis internal orifice size and operative mortality after isolated aortic valve replacement. *J Thorac Cardiovasc Surg*. 2007;133:1012-21.
21. Jin XY, Pepper JR. Do stentless valves make a difference? *Eur J Cardiothorac Surg*. 2002;22:95-100.
22. Bach DS, Kon ND, Dumesnil JG, Sintek CF, Doty DB. Ten-year outcome after aortic valve replacement with the freestyle stentless bioprosthesis. *Ann Thorac Surg*. 2005;80:480-6.
23. Kappetein AP, Puvimanasinghe JP, Takkenberg JJ, Steyerberg EW, Bogers AJ. Predicted patient outcome after aortic valve replacement with Medtronic Stentless Freestyle bioprostheses. *J Heart Valve Dis*. 2007;16:423-8.
24. Ennker JA, Albert AA, Rosendahl UP, Ennker IC, Dalladaku F, Florath I. Ten-year experience with stentless aortic valves: full-root versus subcoronary implantation. *Ann Thorac Surg*. 2008;85:445-52.
25. Funder JA. Current status on stentless aortic bioprosthesis: a clinical and experimental perspective. *Eur J Cardiothorac Surg*. 2012;41: 790-9.
26. Desai ND, Merin O, Cohen GN, Herman J, Mobilos S, Sever JY, et al. Long-term results of aortic valve replacement with the St. Jude Toronto stentless porcine valve. *Ann Thorac Surg*. 2004;78:2076-83.
27. El-Hamamsy I, Clark L, Stevens LM, Sarang Z, Melina G, Takkenberg JJM, et al. Late outcomes following Freestyle versus homograft aortic root replacement: results from a prospective randomized trial. *J Am Coll Cardiol*. 2010;55: 368-76.
28. Bapat V, Attia R, Redwood S, Hancock J, Wilson K, Young C, et al. Use of transcatheter heart valves for a valve-in-valve implantation in patients with degenerated aortic bioprosthesis: technical considerations and results. *J Thorac Cardiovasc Surg*. 2012;144:1372-80.
29. Dvir D, Webb J, Brecker S, Bleiziffer S, Hildick-Smith D, Colombo A, et al. Transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: results from the Global Valve-in-Valve Registry. *Circulation*. 2012; 126:2335-44.
30. Ihlberg L, Nissen H, Nielsen N-E, Rück A, Busund R, Klaarborg K-E, et al. Early clinical outcome of aortic transcatheter valve-in-valve implantation in the Nordic countries. *J Thorac Cardiovasc Surg*. 2013;146:1047-54.
31. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. *J Am Coll Cardiol*. 2000;36:1152-8.
32. Bach DS, Metras J, Doty JR, Yun KL, Dumesnil JG, Kon ND. Freedom from structural valve deterioration among patients aged < or = 60 years undergoing Freestyle stentless aortic valve replacement. *J Heart Valve Dis*. 2007;16: 649-55.
33. Potter DD, Sundt TM 3rd, Zehr KJ, Dearani JA, Daly RC, Mullany CJ, et al. Operative risk of reoperative aortic valve replacement. *J Thorac Cardiovasc Surg*. 2005;129:94-103.
34. Bach DS, Cartier PC, Kon ND, Johnson KG, Deeb GM, Doty DB, et al. Impact of implant technique following freestyle stentless aortic valve replacement. *Ann Thorac Surg*. 2002;74:1107-13.
35. Ennker J, Dalladaku F, Rosendahl U, Ennker IC, Mauser M, Florath I. The stentless freestyle bioprosthesis: impact of age over 80 years on quality of life, perioperative, and mid-term outcome. *J Card Surg*. 2006;21:379-85.

ACD

EDITORIAL COMMENTARY

Do stentless valves make a difference?

John Pepper, MD

See related article on pages 1903-11.

From the Department of Surgery, Royal Brompton Hospital, London, United Kingdom.

Disclosures: Author has nothing to disclose with regard to commercial support.
Received for publication Sept 11, 2014; accepted for publication Sept 12, 2014

Address for reprints: John Pepper, MD, NHR Biological Research Unit, Royal Brompton Hospital, Sydney St, London SW3 6NP, United Kingdom (E-mail: j.pepper@rbht.nhs.uk).

J Thorac Cardiovasc Surg 2014;148:1911-2
0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2014.09.019

In the early 1960s, Ross and Barratt-Boyes separately introduced the aortic homograft into clinical practice. In 1965, Binet and colleagues[1] introduced a stentless porcine bioprosthesis, but this was not pursued because of difficulties with implantation at a time when myocardial protection was in its infancy. Stented bioprostheses were therefore developed because their placement required a much simpler technique and resulted in a reproducible performance. Nevertheless, the transvalvular gradients and limited durability became major concerns. The original free-sewn homograft circumvents most of these problems, but its limited availability prevents its widespread use. This

limitation eventually prompted the reconsideration of a stentless design, intended to reduce residual obstruction of transaortic flow by maximizing the available cross-sectional area. The removal of the stent brought several advantages: (1) a larger valve can be implanted into a given size of aortic annulus, (2) the distensibility and dynamic nature of the aortic annulus is preserved,[2] and (3) it is possible to remodel the native aortic root and preserve the sinotubular junction.

A number of randomized trials have been undertaken to compare stentless with stented valves in the aortic position. Although the effective orifice area of stentless valves is greater and the transvalvular gradients are lower, there is no significant difference in the resolution of left ventricular hypertrophy, as determined by left ventricular mass.[3] It may well be that this is too crude a measurement, and that another instrument such as peripheral blood brain natriuretic peptide or a microRNA signature will be required to show a difference. In the real world of everyday cardiac surgery, however, it has not been possible to show a significant advantage of the stentless porcine valve. A large meta-analysis[4] that examined 17 randomized, controlled trials involving 1317 patients concluded that despite the improved hemodynamics, there had been no impact on patient morbidity, mortality, or resource-related outcomes.

The article by Amabile and colleagues[5] in this issue of the *Journal* is a cohort study that is based on prospectively collected data. Amabile and colleagues[5] report on 500 patients who received a Freestyle valve (Medtronic, Inc, Minneapolis, Minn) in a subcoronary configuration in the majority (479/500). This is one of the largest series reported. The survivals from cardiovascular mortality was 67% for all ages and 83% for patients younger than 65 years. The freedoms from structural valve disease at 10 years were 94% overall and 89% for those younger than 65 years. It is frustrating that we do not have longer follow-up, because the hinge point for the onset of clinically significant structural valve disease is generally around the 12-year mark. It was hoped that the absence of a stent would enhance the durability of a stentless valve, but there is no evidence to support this so far. Amabile and colleagues[5] regret that there are no hemodynamic data, as their patients did not undergo a protocol-led echocardiographic assessment. Nevertheless, these results at 10 years are definitely acceptable.

So what is the indication for the use of a stentless porcine valve in 2014? In the presence of infective endocarditis, it is a reasonable alternative to a homograft to limit the amount of foreign, man-made material.[6] In reoperative aortic surgery, when a root replacement is required, a stentless valve is often an excellent choice of valve substitute. Smith and colleagues[7] have used the Freestyle aortic root prosthesis in the setting of acute aortic dissection. During a 4-year period, 24 of 80 patients received a root replacement with the Freestyle valve. The operative mortality was 25%, and the 5-year survival was 62.5%. During this follow-up period, no patients required reoperative aortic root replacement.

In the Ross operation, where a satisfactory pulmonary homograft may not be available, a Freestyle valve and root is a reasonable alternative provided a large size is chosen. But Hechadi and colleagues[8] sound a word of warning. They used computed tomographic scanning to examine calcification in pulmonary homografts and stentless valves in the right ventricular outflow tract 2 years after the initial operation. They found that calcification occurred in both valve substitutes but progressed more rapidly in the porcine stentless valve. They suggested that the Freestyle valve is an acceptable alternative when a pulmonary homograft is not available.

For a patient wishing to have a hemodynamically superior bioprosthetic valve substitute, the stentless porcine valve is an excellent solution but valve durability is likely to be very similar to that of a stented valve. Reoperative root replacement can be a major undertaking, but valve-in-valve is possible in a stentless porcine valve larger than 25 mm and is associated with a lower 30-day mortality (3% vs 11%).[9] In the current era of transcutaneous aortic valve replacement, however, the Freestyle valve is very suitable for a transcutaneous implant when the valve fails.[10] This can be an attractive option for the patient who wishes to avoid the problems of long-term anticoagulation.

References

1. Binet JP, Duran CG, Carpentier A, Langlois J. Heterologous aortic valve transplantation. *Lancet*. 1965;2:1275-6.
2. Jin XY, Westaby S. Aortic root geometry and stentless porcine valve competence. *Semin Thorac Cardiovasc Surg*. 1999;11:145-50.
3. Perez de Arenaza D, Lees B, Flather M, Nugara F, Husebye T, Jasinski M, et al. Randomized comparison of stentless versus stented valves for aortic stenosis—effects on left ventricular mass. *Circulation*. 2005;112:2696-702.
4. Pepper J, Cheng D, Stanbridge R, Ferdinand FD, Jamieson WR, Stelzer P, et al. Stentless versus stented bioprosthetic aortic valves: a consensus statement of the International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) 2008. *Innovations (Phila)*. 2009;4:61-73.
5. Amabile N, Bical OM, Azmoun A, Ramadan R, Nottin R, Deleuze PH. Long-term results of Freestyle stentless bioprosthesis in the aortic position: a single center prospective cohort of 500 patients. *J Thorac Cardiovasc Surg*. 2014;148:1903-11.
6. Heinz A, Dumfarth J, Ruttman-Ulmer E, Grimm M, Müller LC. Freestyle root replacement for complex destructive aortic valve endocarditis. *J Thorac Cardiovasc Surg*. 2014;147:1265-70.
7. Smith CR, Stamou SC, Hooker RL, Willekes C, Heiser JC, Patzelt LH, et al. Stentless root bioprosthesis for repair of acute type A aortic dissection. *J Thorac Cardiovasc Surg*. 2013;145:1540-4.
8. Hechadi J, Gerber BL, Coche E, Melchior J, Jashari R, Glineur D, et al. Stentless xenografts as an alternative to pulmonary homografts in the Ross operation. *Eur J Cardiothorac Surg*. 2013;44:e32-9.
9. Finch J, Roussin I, Pepper J. Failing stentless aortic valves: redo aortic root replacement or valve in a valve? *Eur J Cardiothorac Surg*. 2013;43:495-504.
10. Bapat V, Davies W, Attia R, Hancock J, Bolter K, Young C, et al. Use of balloon expandable transcatheter valves for valve-in-valve implantation in patients with degenerative aortic bioprostheses: technical considerations and results. *J Thorac Cardiovasc Surg*. 2014;148:917-24.